

ACCOMPANYING LABELING: Leaflets entitled "How Much Do You Really Know About Keeping Physically Fit?" "Exercise is Good Preventive Medicine," "Exercise Does Keep the Weight Down," "Brain Expert Tells Why Strokes Occur," "Fats and Arteries," "Taking it Easy Called Good Way to Get Sick," "Exercise Can Help Your Heart," "10 Myths About Your Health," "Prevent Heart Attacks thru Middle Age Physical Fitness Campaign," "How to Ride Your Exercycle," and "Important to New Users!"; phonograph record "This is Your Life"; folder entitled "Basic Principles of Health and Fitness Guidance"; card entitled "Exercycle Operating Instructions"; and schematic drawing "A Dramatization of the Human System."

RESULTS OF INVESTIGATION: Examination showed the article to be a portable, bicycle-like frame device designed to remain in a fixed position when operating. The unit was equipped with an electric motor which provided power and rhythmic motions, individually or collectively, to the pedals, handlebars, and seat of the device.

LIBELED: 4-20-60, S. Dist. Ohio.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the device was an adequate and effective treatment for increasing circulation of the body, thus helping vital organs to function more efficiently; helping to counteract an increasing death rate from circulatory disorders; helping to overcome or prevent failing eyesight, intestinal disorders, nervousness, body pains and aches, heart attacks, lack of energy and vitality, and brain stroke; helping to prevent ailments not presently evident; that exercise derived from use of the *Exercycle* would reduce the blood cholesterol, thus lowering incidence of hardening of the arteries and possibly other conditions; that exercise derived from use of the *Exercycle* aided in regaining lost youth and health, controlling asthma, recovering from tuberculosis, reducing need for insulin in diabetics, and reducing complications of pregnancy; that the *Exercycle* sales representative was the best informed person on the subject of how one can stimulate his circulation; that exercise derived from use of the *Exercycle* was comparable to such "all-out" exercise as running, swimming, etc.; and that exercise derived from limited daily use of the *Exercycle* contributed significantly to weight reduction.

DISPOSITION: 6-8-61. Consent—claimed by the Exercycle Corp., and released under bond for relabeling.

DRUG ACTIONABLE BECAUSE OF OMISSION OF, OR UNSATISFACTORY, INGREDIENT STATEMENTS*

6820. Vitamin B₁₂ injection. (F.D.C. No. 46484. S. No. 90-995 R.)

QUANTITY: 310 10-cc. unlabeled vials at St. Louis, Mo.

SHIPPED: 5-11-59, from Inwood, Long Island, N.Y., by Bel-Mar Laboratories, Inc.

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 990 micrograms of vitamin B₁₂ per cubic centimeter.

LIBELED: 10-5-61, E. Dist. Mo.

CHARGE: 502(b)—when shipped, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of the contents; 502(e) (1)—the article failed to bear a label containing the common or usual

*See also Nos. 6783, 6784, 6815, 6816.

name of the drug; and 502(e) (2)—the article was fabricated from two or more ingredients, and it failed to bear a label containing the common or usual name of each active ingredient.

DISPOSITION: 12-22-61. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6781 TO 6820

PRODUCTS

	N.J. No.		N.J. No.
Amphetamine sulfate tablets	6792	Lifolic B ₁₂ injection	6796
Androgenic substance	6790	Lumbago, remedies for. <i>See</i>	
Anemia, remedy for	6791	Rheumatism, remedies for.	
Aqua-Spa Whirlpool Bath	6818	Medatinic tablets	6789
Arthritis, remedies for. <i>See</i>		Medcol Cotabs	6789
Rheumatism, remedies for.		Neuralgia, remedies for. <i>See</i>	
Aspirin tablets	6794	Rheumatism, remedies for.	
Beautiqué stockings	6817	Neuritis, remedies for. <i>See</i>	
Bursitis, remedies for. <i>See</i>		Rheumatism, remedies for.	
Rheumatism, remedies for.		Nutri-Kings tablets	6814
Capillaris hair and scalp cream	6815	Pentobarbital sodium capsules	6792
Chick starter and grower	6802	Phenothiazine	6794
Cholester-Sol capsules	6812	Piri-Doxin	6788
Coldene vitamin tonic with iron	6806	Pluraxin vitamin capsules	6787
Con-Care Solution	6797	Poly-Hemin capsules	6791
Contact lens wetting and cleaning solution	6797	Prescription drugs	6783-6786, 6803
Cosmetics (subject to the drug provisions of the Act)	6815-6817	Progeri-Lam capsules	6788
D-7 tablets	6804	Prophylactics, rubber	6798-6800
Derma Culture Formula Nos. 102 and 103	6816	Quto-Electronic Instrument	6793
Devices	6793, 6798-6801, 6816-6819	Rejuvenator	6790, 6807
Diuretic tablets, Ease	6811	Rheumatism, remedies for (drugs)	6809-6811
Ease diuretic tablets	6811	(device)	6818
Electronic device	6793	S-M-C (Sulfur Mineral Concentrate)	6810
Entoquel with Neomycin syrup	6781, 6782	Sarsaparilla tablets	6804
syrup	6781	tea	6804
Eternal Youth face cream	6815	Sciatica, remedies for. <i>See</i>	
Exercycle device	6819	Rheumatism, remedies for.	
Facializer device	6816	Skin disorders, remedy for (device)	6816
H-9 tablets	6804	Stockings, Beautiqué	6817
HB-14 tablets	6804	Sulf-Hydro-Sol	6810
Hair and scalp preparation	6815	Thermometers, clinical	6801
"He-Man" High-Potency Formula	6807	Valer-Relax capsules	6813
Hog builder pellets	6802	Veterinary products	6794, 6802
Huckleberry leaves tea	6804	Vigosan tablets	6790
Hy-Jet Wafers	6789	Vitamin products	6787, 6795, 6796, 6805, 6806, 6808, 6809, 6814, 6820
KB-5 tablets	6804	Whirlpool Bath, Aqua-Spa	6818
L-F-12	6795	Y-min tablets	6805
LGB-4 tablets	6804	Granular	6805

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6821-6860

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *December 5, 1962.*

CONTENTS

	Page
Violative sales of prescription drugs-----	218
	217